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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,840	01/23/2001	Jennifer L. Hillman	PF-0261-2 DIV	2899

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INCYTE GENOMICS, INC.
3160 PORTER DRIVE
PALO ALTO, CA 94304

EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/768,840

Examiner

Chih-Min Kam

Applicant(s)

HILLMAN ET AL.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:
 - I. Claim 1, drawn to a polypeptide comprising an amino acid sequence of SEQ ID NO:1, a sequence having at least 80% sequence homology to SEQ ID NO:1, a biologically active fragment or an immunogenic fragment thereof, classified in class 530, subclass 350.
 - II. Claims 2-12, drawn to an antibody which specifically binds to a polypeptide of claim 1; and a method of preparing the polyclonal or monoclonal antibody, classified in class 530, subclass 387.1.
 - III. Claim 13, drawn to a method of detecting a polypeptide of claim 1 in a sample using an antibody which specifically binds to the polypeptide, classified in class 530, subclass 350, and class 530, subclass 387.1.
 - IV. Claim 14, drawn to a method of purifying a polypeptide comprising SEQ ID NO:1 from a sample using an antibody which specifically binds to the polypeptide, classified in class 530, subclass 350, and class 530, subclass 387.1.
 - V. Claims 15 and 16, drawn to a polynucleotide encoding a polypeptide of claim 1, classified in class 536, subclass 23.1.
 - VI. Claim 17, drawn to a method of detecting a target polynucleotide in a sample, the method comprising hybridizing the sample with a probe comprising a sequence complementary to the target polynucleotide, wherein the probe specifically hybridizes to

Art Unit: 1653

the target polynucleotide to form a hybridization complex, and detecting the presence or absence of the hybridization complex, classified in class 536, subclass 23.1.

VII. Claim 18, drawn to a method of screening for a compound that specifically binds to the polypeptide of claim 1, classified in class 530, subclass 350.

VIII. Claim 19, drawn to a method of screening for a compound that modulates the activity of the polypeptide of claim 1, classified in class 530, subclass 350.

IX. Claim 20, drawn to a method of assessing toxicity of a test compound using a probe comprising at least 20 contiguous nucleotides of a polynucleotide of claim 16, wherein the probe specifically hybridizes to the target polynucleotide to form a hybridization complex, classified in class 536, subclass 23.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a polypeptide, an antibody and a nucleic acid, which are patentably distinct each from the other because they are physically and functionally distinct chemical entities and also have different utilities. For example, polypeptide can be used for studying enzymatic activities, nucleic acid can be used for making probes in northern or southern hybridization and an antibody can be used for western blotting.

The product of Invention I and the methods of Inventions VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with

Art Unit: 1653

another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions VII and VIII are alternative processes of use of the product of Invention I.

The product of Invention II and the methods of Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions III and IV are alternative processes of use of the product of Invention II.

The product of Invention V and the methods of Inventions VI and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions VI and IX are alternative processes of use of the product of Invention V.

The methods of Inventions II, III, IV, VI, VII, VIII and IX are patentably distinct each from the other because they have different method steps, utilize different materials and have different outcomes.

The product of Invention I is distinct from the methods of Inventions II, III, IV, VI and IX because the products of Invention I can be neither made by nor used in the methods of II, III, IV, VI and IX.

Art Unit: 1653

The product of Invention II is distinct from the methods of Inventions VI, VII, VIII and IX because the products of Invention II can be neither made by nor used in the methods of VI, VII, VIII and IX.

The product of Invention V is distinct from the methods of Inventions II, III, IV, VII and VIII because the products of Invention V can be neither made by nor used in the methods of II, III, IV, VII and VIII.

Because Inventions I-IX are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

Art Unit: 1653

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.
Patent Examiner

CMK

February 20, 2003

Karen Cochrane Carlson PhD
KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER